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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,423	05/02/2007	Kazuhiro Chiba	2060.8	7066

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Scott E Hanf
Hammer & Hanf
3125 Springbank Land
Suite G
Charlotte, NC 28226

EXAMINER	
ZALASKY, KATHERINE M	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,423	CHIBA, KAZUHIRO	
	Examiner	Art Unit	
	KATHERINE ZALASKY	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060915*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. **Claims 2 and 4** are rejected under 35 U.S.C. 102(b) as being anticipated by Kostal et al. ("Affinity Purification of Plasmid DNA by Temperature-Triggered Precipitation").

Regarding **claim 2**, Kostal et al. discloses a method of separating a reaction product generated by reaction of a first substance and a second substance (abstract), comprising the steps of:

(a) reacting the first substance with the second substance to generate a reaction product (pg 295, C1, "Results", ¶2, Figure 2, forming plasmid pBLU-Pt)

(b) mixing the reaction product with a temperature-sensitive carrier residing in a liquid-phase state (Figure 1, pg 295/C1, "Results", ¶1, biopolymer ELP153MR, pg 294, C2, "Plasmid Binding")

(c) fixing an anchor region of the reaction product to the temperature-sensitive carrier by converting the temperature-sensitive carrier to a solid-phase state by changing temperature of a reaction system (Figure 1, pg 294/C2, "Plasmid Binding", increasing temperature to 37ºC)

(d) removing impurities from the reaction system (Figure 1, pg 294/C2, "Plasmid Binding", precipitated complex is recovered from mixture)

(e) releasing the anchor region of the reaction product from the temperature-sensitive carrier by converting the temperature-sensitive carrier to a liquid-

phase state by changing temperature of the reaction system (Figure 1, pg 294/C2, "Plasmid Elution and Determination of DNA Content", re-dissolved in buffer on ice, addition of 0.15M NaCl elutes plasmid into liquid, heating to 60 °C precipitates biopolymer, which is removed by centrifugation)

wherein the first substance has an anchor region capable of being fixed to the temperature-sensitive carrier (Pt promoter region) and a reaction region that reacts with the second substance (*Sal*I site, pBLUEscript SK+), and the anchor region is introduced into the reaction product through the reaction between the first and second substances (Figure 2), and wherein the temperature-sensitive carrier is reversibly changed from a solid-phase state to a liquid-phase state by a change in temperature (pg 294, C1/¶1), which fixes the anchor region in the solid-phase state and does not fix the anchor region in the liquid-phase state (pg 294/C2, "Plasmid Binding", "Plasmid Elution and Determination of DNA Content")

Regarding **claim 4**, Kostal et al. discloses a method of separating a complex generated by interaction of a first substance and a second substance (abstract), comprising the steps of:

(a) interacting the first substance with the second substance to generate a complex (pg 295/C1, "Results", ¶2, Figure 2, forming plasmid pBLU-Pt)

(b) mixing the complex with a temperature-sensitive carrier residing in a liquid-phase state (Figure 1, pg 295/C1, "Results", ¶1, biopolymer ELP153MR, pg 294/C2, "Plasmid Binding")

(c) fixing an anchor region of the complex to the temperature-sensitive carrier by converting the temperature-sensitive carrier to a solid-phase state by changing temperature of a reaction system (Figure 1, pg 294/C2, "Plasmid Binding", increasing temperature to 37°C)

(d) removing impurities from the reaction system (Figure 1, pg 294/C2, "Plasmid Binding", precipitated complex is recovered from mixture)

(e) releasing the anchor region of the complex from the temperature-sensitive carrier by converting the temperature-sensitive carrier to a liquid-phase state by changing temperature of the reaction system (Figure 1, pg 294/C2, "Plasmid Elution and Determination of DNA Content", re-dissolved in buffer on ice, addition of 0.15M NaCl elutes plasmid into liquid, heating to 60 °C precipitates biopolymer, which is removed by centrifugation)

wherein the first substance has an anchor region capable of being fixed to the temperature-sensitive carrier (Pt promoter region) and an interaction region that interacts with the second substance (*Sal*I site, pBLUEscript SK+), the anchor region is introduced into the complex through the interaction between the first and second substances (Figure 2), and wherein the temperature-sensitive carrier is reversibly changed from a solid-phase state to a liquid-phase state by a change in temperature (pg 294, C1/¶1), which fixes the anchor region in the solid-phase state and does not fix the anchor region in the liquid-phase state (pg 294/C2, "Plasmid Binding", "Plasmid Elution and Determination of DNA Content")

Claim Rejections - 35 USC § 103

2. **Claims 1 and 3** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba et al. (JP 2003-183298) in view of Chiba et al. (JP 2003-062448, both references are combined/translated in US 2007/0066799).

Regarding **claim 1**, Chiba et al. '799 discloses a method of separating a reaction product generated by reaction of a first substance and a second substance (abstract), comprising the steps of:

(a) mixing the first substance with a temperature-sensitive carrier residing in a liquid-phase state ([0075], cyclohexane with soluble carrier dissolved therein mixing with Fmoc-Val solution at room temperature, heated to form homogeneous solution)

(b) fixing an anchor region of the first substance to the temperature-sensitive carrier by converting the temperature-sensitive carrier to a solid-phase state by changing temperature of a reaction system ([0075], reaction solution was cooled and the cyclohexane layer, with the soluble carrier bonded with Val-NH_2, was separated, [0046], may be separated as a solid)

(c) generating a reaction product by reacting the second substance with a reaction region of the first substance that is fixed to the temperature-sensitive carrier ([0076], Fmoc-Gly in solution mixed with 2 mL of solution having [SC]-Val-NH_2/cyclohexane, heated to 50°C and then cooled again to separate, [0046])

(d) removing impurities from the reaction system ([0075], [0046])

(e) releasing the anchor region of the reaction product from the temperature-sensitive carrier by converting the temperature-sensitive carrier to a liquid-phase state by changing temperature of the reaction system ([0046], separated solid is heated to vaporize and removed cyclohexane, leaving only the desired peptide product)

wherein the first substance has an anchor region capable of being fixed to the temperature-sensitive carrier (soluble carrier region, Scheme pg 5-6) and a reaction region that reacts with the second substance (NH_2 group, [0075]-[0076]), and wherein the temperature-sensitive carrier is reversibly changed from a solid-phase state to a liquid-phase state by a change in temperature ([0043], [0046]), which fixes the anchor region in the solid-phase state and does not fix the anchor region in the liquid-phase state ([0075], [0076], [0046] becomes a homogeneous solution when heated which allows peptide product to be separated)

Regarding **claim 3**, Chiba et al. '799 discloses a method of separating a complex generated by interaction of a first substance and a second substance (abstract), comprising the steps of:

(a) mixing the first substance with a temperature-sensitive carrier residing in a liquid-phase state ([0075], cyclohexane with soluble carrier dissolved therein mixing with Fmoc-Val solution at room temperature, heated to form homogeneous solution)

(b) fixing an anchor region of the first substance to the temperature-sensitive carrier by converting the temperature-sensitive carrier to a solid-phase state

by changing temperature of a reaction system ([0075], reaction solution was cooled and the cyclohexane layer, with the soluble carrier bonded with Val-NH_2, was separated, [0046], may be separated as a solid)

(c) generating a complex by interacting the second substance with an interaction region of the first substance that is fixed to the temperature-sensitive carrier ([0076], Fmoc-Gly in solution mixed with 2 mL of solution having [SC]-Val-NH_2/cyclohexane, heated to 50°C and then cooled again to separate, [0046])

(d) removing impurities from the reaction system ([0075, [0046])

(e) releasing the anchor region of the complex from the temperature-sensitive carrier by converting the temperature-sensitive carrier to a liquid-phase state by changing temperature of the reaction system ([0046], separated solid is heated to vaporize and removed cyclohexane, leaving only the desired peptide product)

wherein the first substance has an anchor region capable of being fixed to the temperature-sensitive carrier (soluble carrier region, Scheme pg 5-6) and an interaction region that can interact with the second substance (NH_2 group, [0075]-[0076]), and wherein the temperature-sensitive carrier is reversibly changed from a solid-phase state to a liquid-phase state by a change in temperature ([0043], [0046]), which fixes the anchor region in the solid-phase state and does not fix the anchor region in the liquid-phase state ([0075], [0076], [0046] becomes a homogeneous solution when heated which allows peptide product to be separated)

Regarding **claims 1 and 3**, Chiba et al. '298 discloses everything cited above (machine translation, [0007], [0020]-[0022]), but does not explicitly disclose that the anchor region is released from the carrier by changing the temperature. However, Chiba '448 discloses that when cyclohexane is in a solid form with a desired product, the product may easily be separated out by heating the solid to release the product and evaporate the cyclohexane (machine translation, [0014]). Therefore, it would have been obvious to one having ordinary skill in the art to solidify and separate the cyclohexane and peptide product from the solution, once the peptide synthesis is complete, and then heat the solid until the cyclohexane is evaporated off in the method of Chiba et al. '298, as taught by Chiba '448, since doing so provides a purified, isolated peptide product which is free of solvent.

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on Monday-Thursday, 7:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KZ/
19 May 2009

/Krishnan S Menon/
Primary Examiner, Art Unit 1797